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Customer No. 23990

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Ronald A. Schachar

Serial No.: 09/556,143

Filed: April 21, 2000

Title: SEGMENTED SCLERAL BAND FOR TREATMENT OF
PRESBYOPIA AND OTHER EYE DISORDERS

Examiner: David M. Shay

Art Group Unit: 3735

MAIL STOP AF

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

PRE-APPEAL BRIEF REQUEST FOR REVIEW

The Applicant hereby requests review of the final rejection in the above-identified application. No amendments are being filed with this request. This request is being filed with a Notice of Appeal. The review is requested for the reasons stated in the arguments below, demonstrating the clear legal and factual deficiency of the rejection of some or all claims.

Claims 40-59 stand rejected under 35 U.S.C. § 102(b) as being anticipated by March et al., "Safety of High-Energy Neodymium:YAG Laser Pulses in YAG Sclerostomy" ("*March*").

Claim 40 recites a method that includes:

irradiating a sclera of an eye in a region of a ciliary body to
thereby weaken the sclera of the eye and increase an effective
working distance of a ciliary muscle of the eye;
wherein irradiating the sclera comprises reducing a thickness
of the sclera in the region of the ciliary body without forming an
opening completely through the sclera.

March discloses a technique for treating glaucoma using a pulsed laser. (Page 584, Left column, Introduction). This “new” technique actually forms a channel (called a “fistula”) completely through the sclera of a patient’s eye. (Figure 6). This contrasts with prior techniques discussed in *March*, which failed to form a channel completely through the sclera. (Page 586, Right column). *March* therefore discusses both its “new” treatment (which forms a complete scleral perforation) and various “previous” treatments (which failed to form a complete scleral perforation).

Claim 40 clearly notes that irradiating the sclera includes reducing a thickness of the sclera in a particular region “without forming an opening completely through the sclera.” As a result, Claim 40 specifically prohibits the result produced by the “new” treatment of *March*.

Therefore, there are only two disclosures in *March* that the Examiner could possibly rely upon as anticipating Claim 40. The first deals with the discussion in *March* regarding the “previous” treatments that failed to form a complete scleral perforation. The second deals with the brief period of time between the first laser pulse and the last laser pulse during the “new” treatment in *March* (in other words, after the “new” treatment begins but prior to the formation of a complete scleral perforation during the “new” treatment).

In either case, the Examiner simply assumes that the “laws of physics” require that *March* inherently weakens the sclera since tissue is removed from the sclera in *March*. Based on that assumption, the Examiner assumes that since the eye is weaker, “this necessarily requires that the structure will expand due to the internal pressure thereof in combination with [its] weakened state.” (12/15/06 Office Action, Page 3, Last paragraph; 12/20/07 Office Action, Page 3, Last paragraph). However, the Examiner fails to satisfy the burden of proving inherency as required by MPEP § 2112.

The Examiner has never shown that *March* removes adequate tissue to weaken the sclera of a

patient's eye. The Examiner has never shown that the amount of tissue actually removed in *March* would enable scleral expansion in the patient's eye. The Examiner has never shown that the amount of tissue actually removed in *March* would allow for an increase in the effective working distance of a ciliary muscle in the patient's eye. The Examiner has simply assumed that *March* weakens the sclera, assumed that this weakening is adequate to cause scleral expansion, and assumed that this expansion is adequate to cause an increase in the effective working distance of the ciliary muscle.

It is well-established that inherency cannot be established by "probabilities or possibilities." Rather, the burden is on the Examiner to establish that both scleral weakening and an increase in the effective working distance of the ciliary muscle are "necessarily present" in *March*. The fact that this "may occur or be present" in *March* is not sufficient to establish inherency. (See MPEP § 2112).

Regarding the "previous" treatments in *March*, *March* never actually describes those treatments. Specifically, *March* never discloses the exact locations of laser irradiation in the prior treatments, the amount of tissue removed during those prior treatments, or any other details of those prior treatments. The Examiner cannot establish that this discussion in *March* inherently anticipates "irradiating a sclera of an eye ... to thereby weaken the sclera of the eye and increase an effective working distance of a ciliary muscle of the eye," where this is done "without forming an opening completely through the sclera." Nothing in *March* indicates that an adequate amount of tissue is removed to weaken the sclera or increase the ciliary muscle's effective working distance.

Similarly, the "new" treatment of *March* merely involves using a pulsed laser. The Examiner cannot possibly establish that, for the brief period between the start of laser treatment and the complete formation of a scleral perforation, *March* inherently anticipates "irradiating a sclera of an eye ... to thereby weaken the sclera of the eye and increase an effective working distance of a ciliary

muscle of the eye,” where this is done “without forming an opening completely through the sclera.” The Examiner has never even attempted to show that an adequate amount of tissue is removed during the “new” treatment of *March* to weaken the sclera or increase the ciliary muscle’s effective working distance during this brief period of time.

The Examiner’s reliance on unnamed “laws of physics” is improper. The Examiner has never cited any law of physics that says “any material removed from any structure in any way weakens the structure.” More importantly, the Examiner has never cited any law of physics that says “any material removed from any part of an eye in any way weakens the eye and allows scleral expansion and an increase in the ciliary muscle’s effective working distance.” The Examiner instead asserts that this must be true since “were the reverse true, structures made of no material at all would be as strong or stronger as a structure which did contain material.” (*06/25/08 Advisory Action, Page 2*). This clearly is a strawman argument – the Examiner is making a proposition (not asserted by the Applicant) and then arguing against it as proof of his own inherency argument. However, the proposition made by the Examiner does not support the Examiner’s inherency argument in any way. The Examiner needs to present actual proof (not mere “probabilities or possibilities”) that the removal of tissue specifically disclosed in *March* actually weakens the sclera and allows an increase in the ciliary muscle’s effective working distance. The Examiner has not made this showing as specifically required by MPEP § 2112.

Moreover, the Examiner improperly places the burden of disproving inherency on the Applicant, rather than placing the burden of proving inherency on the Office. The Examiner has never shown that *March* removes an adequate amount of tissue to weaken the sclera of an eye and increase the ciliary muscle’s effective working distance. The Examiner has simply assumed that

March removes adequate tissue, assumed that this would weaken the sclera, and assumed that this would allow an increase in the effective working distance of the ciliary muscle. The Examiner has then left it up to the Applicant to disprove this series of assumption. However, MPEP § 2112 places the burden of proving inherency on the Examiner, and the Examiner has not met this burden.

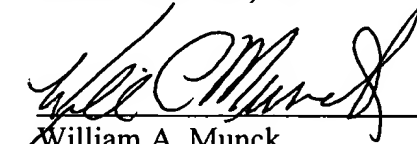
For these reasons, the Examiner's rejection of Claim 40 under § 102 in view of *March* is improper. The Examiner has failed to satisfy the legal and factual requirements for establishing inherency as required by MPEP § 2112. For one or more of these reasons, the Examiner's rejection of Claims 47 and 54 (the other independent claims) under § 102 in view of *March* is also improper.

The Examiner has made several statements regarding possible enablement issues with the Applicant's disclosure. However, there are currently no outstanding enablement rejections. Until the Examiner actually issues an enablement rejection that satisfies the requirements of MPEP § 2164, the Examiner's statements regarding enablement are not relevant, and the Examiner's statements regarding enablement are not relevant to the issue of inherency at any point.

The Commissioner is hereby authorized to charge any fees connected with this communication or credit any overpayment to Deposit Account No. 50-0208.

Respectfully submitted,

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